DOCKET NO.: CEPH-2249/CP241 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Craig Heacock, et al.
Application No.: 10/616,776
Filing Date: July 10, 2003

Confirmation No.: 1994
Group Art Unit: 1615
Examiner: Not Yet Assigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF FACTS IN SUPPORT OF PETITION TO MAKE SPECIAL BECAUSE OF ACTUAL INFRINGEMENT (MPEP § 708.02)

I, Craig S. Heacock, Ph.D., of Cephalon, Inc., 41 Moores Road, P.O. Box 4011, Frazer, PA, 19355

☐ am the inventor;

☒ have the following interest or relationship to the above identified patent application: I am an inventor of the claimed subject matter, and I am the Vice President of Pharmaceutical Development for Cephalon, Inc., the application's assignee,

and on information and belief I hereby allege that:

1. The inventions recited in claims 134 and 137 to 139 of the patent application relate to oral dosage units of modafinil wherein more than about 5% of the modafinil particles in the dosage unit have diameters greater than 220 microns. The dosage unit is bioequivalent to a modafinil dosage unit in which at least about 95% of the modafinil particles have diameters

less than about 200 microns. Dependent claim 137 specifies that the oral dosage unit contains 100 mg of modafinil, and is bioequivalent to a 100 mg dosage unit in which at least about 95% of the particles are smaller than about 200 microns. Dependent claim 138 specifies that the oral dosage unit contains 200 mg of modafinil, and is bioequivalent to a 200 mg dosage unit in which at least about 95% of the particles are smaller than about 200 microns. Dependent claim 139 is directed to oral dosage units of claim 138 that it are bioequivalent to the modafinil drug product identified by the Food and Drug Administration (FDA) as the reference listed modafinil drug. Claims 140 to 145 are directed to methods of treatment using the oral dosage units. In particular, the oral dosage unit may be used to treat narcolepsy.

2. Cephalon, Inc. presently markets the modafinil product Provigil®, which is approved by the FDA under NDA No. 20-717 for the treatment of narcolepsy and other conditions. The Provigil® product is available in 100 mg and 200 mg oral dosage units. Both of these Provigil® oral dosage units comprise modafinil particles, and at least about 95% of those particles have diameters less than about 200 microns. The 200 mg Provigil® product is the modafinil drug product identified by the FDA as the reference listed drug product.

3. Cephalon, Inc. is the owner of U.S. Patent No. RE37,516 E, issued January 15, 2002 ("the '516 patent"). The '516 patent is directed, *inter alia*, to oral unit dose forms and methods of treatment using same, wherein the oral unit dose forms comprise modafinil in the form of solid modafinil particles, and wherein at least about 95% of the cumulative total of said particles have a diameter of less than about 200 microns. Cephalon, Inc. has listed this patent in the FDA's *Approved Drug Produces with Therapeutic Equivalence Evaluation* ("the Orange Book") under NDA No. 20-717.

4. Several pharmaceutical manufacturers have filed Abbreviated New Drug Applications (ANDAs) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act

(FDCA) seeking FDA approval to market modafinil drug products. As part of these applications, the manufacturers have certified under FDCA Section 505(j)(2)(A)(vii), paragraph IV that the '516 patent is invalid or will not be infringed by the modafinil products that are the subject of the ANDAs.

5. One such generic pharmaceutical manufacturer is Ranbaxy Laboratories Limited ("RLL"). Pursuant to filing its ANDA, RLL notified Cephalon, in a letter dated March 21, 2003 (copy attached hereto as Exhibit A), that it had filed a paragraph IV certification. Shortly after receiving this notification, Cephalon sued RLL and the other ANDA filers for infringement of the '516 patent (*inter alia)* under 35 U.S.C. § 271(e)(2). That litigation is ongoing.

6. In its letter dated March 21, 2003, RLL states that its ANDA is filed under FDCA Section 505(j) and contains data establishing bioequivalence or bioavailability in order to obtain approval to engage in the commercial manufacture, use or sale of a drug product containing modafinil. Exhibit A at page 1. The letter further states that RLL's drug products are in the form of tablets which contain 100 or 200 mg of modafinil. *Id.* The letter asserts that RLL's drug products will not infringe any claim of the '516 patent because the products will not meet the patent's requirement that "at least about 95% of the cumulative total of said particles have a diameter of less than about 200 microns."

7. The RLL letter states that the product for which it seeks approval "will be prepared from mixtures of solid modafinil particles" and "will contain, as more than 10% of the cumulative total of their modafinil particles, solid modafinil particles with diameters of greater than 250 microns." *Id.* at page 13. The letter also asserts that "RLL's drug product will necessarily exhibit distributions in which more than 10% (twice the 5% threshold) of the cumulative total of modafinil particles will have diameters of at least 250 microns," (*id,*

paragraph bridging pages 13 and 14; emphasis in original), indicating that the product for which approval is being sought will meet the requirement in claim 134 that more than about 5% of the modafinil particles in the dosage unit have diameters greater than 220 microns..

8. The statements made in RLL's letter dated March 21, 2003, establish that RLL is seeking approval to engage in the commercial manufacture, use or sale of 100 mg and 200 mg modafinil-containing tablets that are bioequivalent to 100 mg and 200 mg Provigil® tablets. The 200 mg Provigil® tablets are the product identified by the FDA as the reference listed modafinil drug, and at least about 95% of the modafinil particles in both 100 mg and 200 mg Provigil® tablets have diameters less than about 200 microns. RLL's statements further establish that more than about 5% of the modafinil particles in the dosage unit will have diameters greater than 220 microns. It is thus evident that the modafinil products that are the subject of RLL's ANDA are within the scope of at least claims 134 and 137 to 145 of the referenced application.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: December 14, 2005

Craig S. Heacock, Ph.D.
Vice President, Pharmaceutical Development
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